

IAP7 Rec'd PCTA 27 FEB 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Tebareye Biftu, et al.

Serial No. 10/556,805

Filed: November 14, 2005

For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES  
AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE  
TREATMENT OR PREVENTION OF DIABETES

Art Unit: To Be Assigned

Examiner: To Be Assigned

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK &amp; CO., INC.

By Devere Brown Date 2/21/07

## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

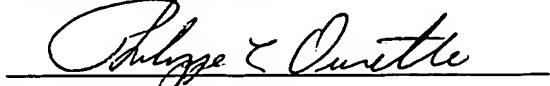
<b>RELATED APPLICATION</b>		
<b>U. S. SERIAL NUMBER</b>	<b>FILING DATE</b>	<b>MERCK CASE</b>
10/540,283	June 20, 2005	21304YP
10/537,476	June 3, 2005	21288YP
10/530,215	April 4, 2005	21239YP
10/542,694	July 19, 2005	21329YP

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- the attached information is filed within three months of the filing date of the captioned case.
- the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Philippe L. Durette

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 35,125

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

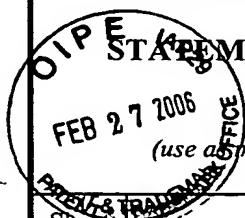
Rahway, N.J. 07065-0907

(732)594-4568

Date: February 13, 2006

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## **INFORMATION DISCLOSURE**



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of

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**COMPLETE IF KNOWN**

Application Number	10/556,805
Filing Date	November 14, 2005
First Named Inventor	Tesfaye Biftu, et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	21404P

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
8	PCT	WO 03/082817 A2			MERCK & CO., INC.	10/09/2003
9	PCT	WO 03/000180 A2			MERCK & CO., INC.	01/03/2003
10	PCT	WO 03/000181 A2			MERCK & CO., INC.	01/03/2003
11	PCT	WO 03/000181 A3			MERCK & CO., INC.	01/03/2003
12	PCT	WO 02/076450 A1			MERCK & CO., INC.	10/03/2002
13	PCT	WO 2004/007468 A1			MERCK & CO., INC.	01/22/2004
14	PCT	WO 2004/032836 A2			MERCK & CO., INC.	04/22/2004
15	PCT	WO 2004/050022 A2			MERCK & CO., INC.	06/17/2004
16	PCT	WO 2004/058266 A1			MERCK & CO., INC.	07/15/2004
17	PCT	WO 2004/064778 A2			MERCK & CO., INC.	08/05/2004

**Examiner  
Signature**

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE</b></p> <p><b>STATEMENT BY APPLICANT</b></p> <p><i>(use as many sheets as necessary)</i></p>				<b>COMPLETE IF KNOWN</b>	
				Application Number	10/556,805
				Filing Date	November 14, 2005
				First Named Inventor	Tesfaye Biftu, et al.
				Group Art Unit	
				Examiner Name	
Sheet	2	of	5	Attorney Docket Number	21404P

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		Office	Number	Kind Code (if known)		
18	PCT	WO 2004/069162 A2			MERCK & CO., INC.	08/19/2004
19	PCT	WO 02/02560 A2			NOVO NORDISK A/S	01/10/2002
20	PCT	WO 01/96295 A2			NOVARTIS AG	12/20/2001
21	PCT	WO 01/96295 A3			NOVARTIS AG	12/20/2001
22	PCT	WO 01/34594 A1			Guilford Pharmaceuticals, Inc.	05/17/2001
23	PCT	WO 00/34241			NOVARTIS AG	06/15/2000
24	PCT	WO 98/19998 A2			NOVARTIS AG	05/14/1998
25	PCT	WO 98/19998 A3			NOVARTIS AG	05/14/1998
26	PCT	WO 97/40832			Hansknoll-Institut Fur Naturstoff-Forschung E.V.	11/06/1997
27	PCT	WO 03/000180 A3			MERCK & CO., INC.	01/03/2003

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Sheet 3 of 5 Attorney Docket Number 21404P

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		Office	Number	Kind Code (if known)		
28	PCT	WO 02/02560		A3	NOVO NORDISK	01/10/2002
29	PCT	WO 01/42262			AKZO NOBEL N.V.	06/14/2001
30	PCT	WO 2004/043940			MERCK & CO., INC.	05/27/2004
31	PCT	WO 2004/007468			MERCK & CO., INC.	01/22/2004
32	PCT	WO 2004/110436			MERCK & CO., INC.	12/23/2004
33	PCT	WO 2004/112701		A2	MERCK & CO., INC.	12/29/2004
34	PCT	WO 2004/112701		A3	MERCK & CO., INC.	12/29/2004
35	PCT	WO 2005/011581		A2	MERCK & CO., INC.	02/10/2005
36	PCT	WO 2005/044195		A2	MERCK & CO., INC.	05/19/2005
37	PCT	WO 2005/002530		A2	SMITHKLINE BEECHAM CORP.	01/09/2003

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

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**Attorney Docket Number**

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		Office	Number	Kind Code (if known)		
38	PCT	WO 2005/056003		A1	GRAFFINITY PHARMACEUTICALS AG	06/23/2005
39	PCT	WO 2005/056013		A1	GRAFFINITY PHARMACEUTICALS AG	06/23/2005
40	PCT	WO 2005/108382		A1	MERCK & CO., INC.	11/17/2005
41	PCT	WO 2005/116029		A1	MERCK & CO., INC.	12/08/2005
42	PCT	WO 2005/123685		A1	ASTRAZENECA AB	12/29/2005

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## STATEMENT BY APPLICANT

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Sheet	5	of	5	Attorney Docket Number	21404P
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### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.			
	43	J. J. Holst, "Treatment of Type 2 Diabetes Mellitus with Agonists of the GLP-1 Receptor or DPP-IV Inhibitors", Expert Opin. Emerg. Drugs, Vol. 9(1) pp. 155-166(2004).			
	44	C. F. Deacon, et al., "Inhibitors of dipeptidyl peptidase IV: A Novel Approach for the Prevention and Treatment of Type 2 Diabetes?", Expert Opin. Investig. Drugs, Vol. 13(9) pp. 1091-1102( 2004).			
	45	K. Augustyns et al., " Dipeptidyl Peptidase IV Inhibitors as New Therapeutic Agents for the Treatment of Type 2 Diabetes", Expert Opin. Ther. Patents, Vol. 13(4), pp. 499-510(2003).			
	46	Novartis AG: WO0034241, "Novel N-substituted-2-Cyanopyrrolidines as Potent Inhibitors of Dipeptidyl Peptidase IV in the Treatment of Non-Insulin-Dependent Diabetes Mellitus", Exp. Opin. Ther. Patents, Vol. 10(12), pp. 1937-1942 (2000).			
	47	O. J. Orucker, "Therapeutic potential of dipeptidyl peptidase IV inhibitors for the treatment of type 2 diabetes", Exp. Opin Invest. Drugs, Vol.12, pp. 87-100 (2004).			
	48	T. P. Vahl & D. A. D'Alessio, "Gut peptides in the treatment of diabetes mellitus" Exp. Opin. Invest. Drugs, Vol. 13, pp. 177-188 (2004).			
	49	L. B. Knudsen, "Glucagon-like peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes", J. Med. Chem, Vol. 47, pp. 4128-4134 (2004).			
	50	A. E. Weber, "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes", J. Med. Chem, Vol. 47, pp. 4135-4141 (2004).			
	51	J. J. Holst and C. F. Deacon, "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus", Curr. Opin Pharmacology, Vol. 4, pp. 589-596 (2004).			
	52	C. F. Deacon, "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1", Diabetes, Vol. 53, pp. 2181-2189 (2004).			
	53	K. Augustyns, et al., "Inhibitors of proline-specific dipeptidyl peptidase: DPP IV inhibitors as a novel approach for the treatment of Type 2 diabetes", Expert Opin. Ther. Patents, Vol. 15(10), pp. 1387-1407 (2005).			
	54	Hans-Ulrich Demuth, et al., " Type 2 diabetes - Therapy with dipetidyl peptidase IV inhibitors", Biochimica et Biophysica Acta, Vol. 1751, pp. 33-44 (2005).			

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